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CURRENT LIMITING SAFETY ELECTRODE LEAD

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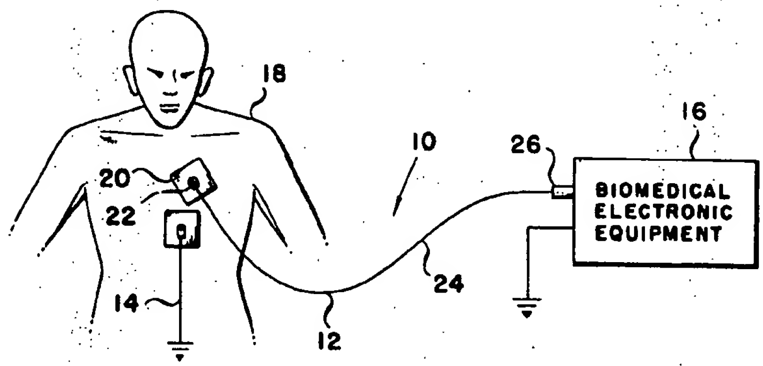


FIG. 1

FIG. 2

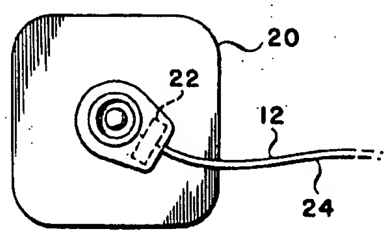
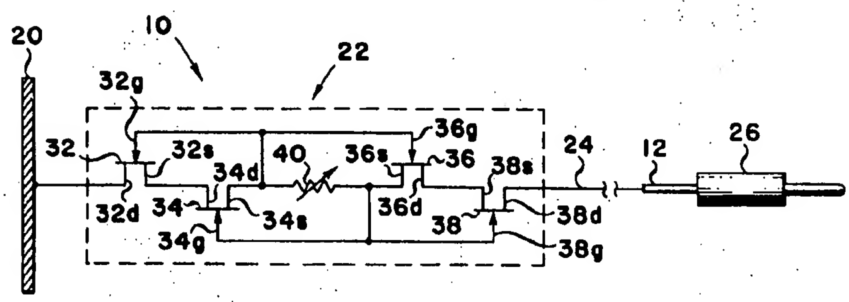


FIG. 3



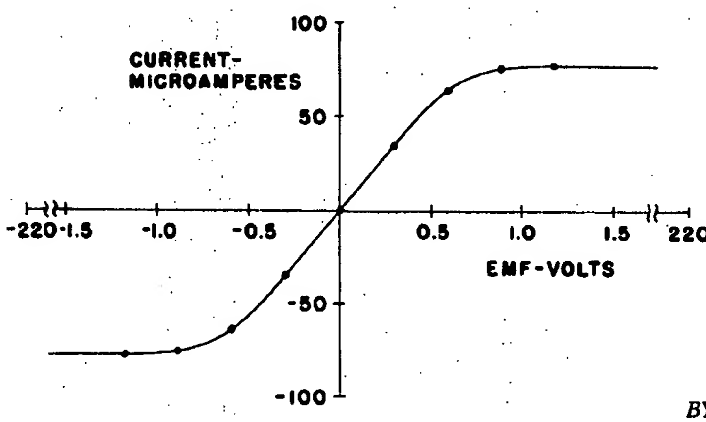


FIG. 4

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CURRENT LIMITING SAFETY ELECTRODE LEAD

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ABSTRACT OF THE DISCLOSURE

A safety lead system for the transmission of bioelectrical signals from a patient to biomedical electronic equipment and for patient grounding. Each lead has an integral unpowered semiconductor current limiting circuit at the electrode which provides linear low impedance transmission of the bioelectrical signal but limits current flow through the lead to a preset maximum level below that which is harmful to the patient, regardless of the polarity and intensity of accidentally applied currents and voltages.

The present invention relates to a safety electrode lead system and more particularly to biomedical electrode leads with integral current limiting circuitry.

There is a safety hazard involved in the use of patient body electrode leads. The body electrodes typically have a low resistance connection to the patient. This exposes the patient to the danger of electrical shock or electrocution from even very low currents and voltages accidentally applied through the electrodes. Such accidentally applied currents may arise from various possible failures or defects in the connected biomedical electronic equipment or in the lead itself, or arise from accidental application of line voltage or electrostatic charges to the patient or lead, etc.

Various protective circuitry has been previously developed for the internal circuitry of the connected biomedical equipment. However, it has been found that this does not provide adequate patient protection, as at best it can only protect against electrical hazards arising internally in the connected equipment, which is only one of the abovementioned sources of electrical hazard.

In contrast, the safety lead system of the present invention positively limits the electrical current which can flow through a body electrode to a safe level, regardless of the source or polarity of the current accidentally applied. The present application discloses a novel miniature current limiting circuit directly integrated into each electrode lead at the body electrode. The circuit is a simple, stable and reliable arrangement providing both voltage and current overload protection, and utilizing known semiconductor components (see e.g. "FET Applications Handbook," J. Eimbinder, Editor, TAB Books, 1967.) Protection is provided against both DC and alternating currents, including fully applied 220 volt line current. The limiting current level in each lead may be readily preselected (simply by changing the value of one resistor) to provide patient protection for the number, placement and type of electrodes to be utilized. For externally applied electrodes the current limit may be set to 200 microamperes to prevent any possibility of currents in excess of that value from being applied to the patient. For skin penetrating needle, wire, or other internally connected electrodes the maximum current level may be set to 10 microamperes or lower to provide maximum protection. These current limiting levels are achieved without any degradation of the bioelectrical signals from the patient, as the leads of the invention present only a low and linear series resistance to the bioelectric signals. The leads may be directly substituted for existing electrode leads on most existing biomedical electronic devices, even those with relatively low input impedances.

Further objects, features and advantages of the invention pertain to the particular arrangement and structure whereby the above-mentioned aspects of the invention are attained. The invention will be better understood by reference to the following description and to the drawings forming a part hereof, which are substantially to scale, wherein:

FIG. 1 illustrates an exemplary body electrode lead system in accordance with the present invention;

FIG. 2 is a large partial plan view of an exemplary body electrode lead of the system of FIG. 1;

FIG. 3 is a schematic circuit diagram of an electrode lead of FIGS. 1 and 2; and

FIG. 4 is a plot of current-voltage characteristics of an electrode lead of FIGS. 1–3.

Referring to the drawings, FIGS. 1–4, there is shown therein an exemplary safety electrode lead system 10 in accordance with the present invention. For clarity of description there is shown herein only one instrument lead 12 connected to only one piece of biomedical electrical equipment 16 and only one ground lead 14. It will be appreciated that the invention is intended to be utilized in any of the various conventional multiple electrode placement arrangements used in any appropriate biomedical instrumentation as, for example, EEG or EKG measurements. The biomedical electronics equipment 16 may be any new or existing biomedical electronic equipment utilizing a connection with human or animal body electrodes for receiving bioelectrical signals. A generally conventional body electrode 20 of the snap-on type is illustrated here, wherein the actual skin contact member is removable from the electrode end of the lead. It will be appreciated that the invention contemplates any type of body electrode, with or without removable contact members, and whether external or internal. The current limiting level will be preset in accordance with the type and placement of the electrode since the type of electrode and its application point will determine the maximum safe current level through the lead. The instrument lead 12 and the ground lead 14 are preferably substantially identical, and accordingly the following description is of the instrument lead 12, with the understanding that all other leads utilized in the system will have substantially the same structure, although the preset current limiting level may vary. The term "lead" as used herein refers to an individual wire lead, not to a wire pair.

The lead 12 here comprises a conventional elongate and flexible electrical conductor 24 with a body electrode 20 at one end and a conventional electrical connector 26 at the opposite end for connection of the lead to the biomedical electronic equipment 16. The lead 12 integrally includes a miniature unpowered transistor current limiting circuit 22 in the lead, preferably in the end having the body electrode 20. This current limiting circuit 22, shown in detail in FIG. 3, prevents current flow

in both directions through the lead 12 from exceeding a preselected current limiting level. This current level is limited independently of the polarity and potential of the current and voltage applied to said lead 12 from any source, including current applied directly to the conductor 24. The current limit level is selected and preset in the current limiting circuit 22 to be less than maximum safe current level for a patient 18 connected to the body electrode 20. The lead 12, by means of the current limiting circuit 22, provides a substantially linear impedance conductive path for all bioelectric signals from the body electrode 20 to the connector 26. The current limiting circuit 22 is electrically connected directly in series between the body electrode 20 and the conductor 24, and no parallel current path which could bypass the current limiting circuit 22 is present.

The entire current limiting circuit 22 is adapted to fit in any desired miniature packaging arrangement. Preferably, as indicated in FIG. 2, the circuit 22 is packaged directly in the head of the body electrode 20 so as to be as close to the actual patient contact area as possible. Thus, excessive currents are prevented from flowing to or from the patient 18 by accidental currents imposed anywhere in the flexible conductor 24, the connector 26, or the biomedical electronic equipment 16.

Considering in detail the construction, interconnection and operation of the current limiting circuit 22 illustrated in FIG. 3, it may be seen that the circuit 22 employs only five components, a resistor 40 and four N channel field effect transistors (FET's) 32, 34, 36, and 38. Although junction FET's are indicated, insulated gate FET's may be used in the same manner. Similarly, P channel FET's may also be used. All five elements are connected in series between the body electrode 20 and the flexible conductor 24. The FET's 32 and 34 are connected between the electrode 20 and the resistor 40, while the FET's 36 and 38 are connected between the resistor 40 and the conductor 24.

The drain lead 32*d* of FET 32 is connected to the electrode 20. The gate lead 32*g* is connected to the near or electrode side of the resistor 40 and also to the gate lead 36*g* of the FET 36, and to the source lead 34*s* of the FET 34. The source lead 32*s* of the FET 32 is connected to the drain lead 34*d* of the FET 34. The gate lead 34*g* of FET 34 is connected to the far or equipment side of the resistor 40 and also interconnects with the source lead 36*s* of the FET 36 and the gate lead 38*g* of the FET 38. The drain lead 36*d* of FET 36 is connected to the source lead 38*s* of FET 38 and the drain lead 38*d* of FET 38 is connected to conductor 24. It may thus be seen that a continuous series circuit is provided through the current limiting circuit 22 by the series connection of the following components: the FET 32 between its drain 32*d* and source 32*s*, the FET 34 between its drain 34*d* and its source 34*s*, the resistor 40, the FET 36 between its source 36*s* and its drain 36*d*, and the FET 38 between its source 38*s* and its drain 38*d*. The body electrode 20 is connected to the drain lead 32*d* of the FET 32 at one end of the circuit 22 and the flexible conductor 24 connects with the FET 38 at its drain lead 38*d* at the opposite end. It may be seen that the resistor 40 connects between the source 34*s* and gate 34*g* of FET 34. The same is true for FET 36.

Exemplary suitable components are Amelco 2N4882 high voltage FET's for FET's 32 and 38, Siliconix FN 1598 for FET's 34 and 36, and a 3.3K ohms resistor for the resistance 40. This provides a current limiting value of 100 microamperes which is not exceeded by any applied voltage between ±300 volts. These components may all be obtained in quantity for a total cost of approximately $14.00.

The current limiting circuit 22 prevents current in excess of a preselected limiting level or value from flowing in either direction. For all electrical currents less than the limiting value currents are allowed to flow through the circuit 22 according to a linear resistance which is sufficiently low not to interfere in any way with normal signal transmissions. Essentially, there are two independent current limiting circuits, each operating in one current direction (polarity) but having one common element, the resistor 40. In one direction the current limiting is provided by the FET's 32 and 34 and the resistor 40. This limits the current in the direction corresponding to a positive voltage on electrode 20 with respect to the conductor 24. In the opposite current direction, corresponding to a positive voltage on flexible lead 24, the current limiting function is accomplished through the FET's 36 and 38 and the resistor 40.

Considering the operation with electrode 20 positive, the current limiting value is determined by FET 34 and resistor 40. The characteristic required for FET 34 is a low pinchoff voltage (V_p) of below 0.5 volt for silicon junction FET's. V_p is herein defined as the gate-to-source (34*g* to 34*s*) voltage for which the drain-to-source (34*d* to 34*s*) current is limited to the desired limiting current value for any normal (non-overload) drain-to-source voltage. For small currents (below the limiting value) the voltage drop across resistor 40 is small relative to V_p, and FET 34 is in its linear resistance region. As the positive voltage applied to the electrode 20 increases, the current through, and therefore the voltage across, resistor 40 increases until the voltage across resistor 40 reaches V_p. FET 34 then begins to limit and additional applied voltage is dropped between the drain and source of FET 34. Thus, the current through the circuit 22 is substantially independent of the applied voltage, i.e., is limited to the limiting value, for applied voltages ranging from slightly greater than V_p up to the breakdown voltage of FET 34.

The voltage across resistor 40 at the current limiting value should not be greater than about .5 volt for junction FET's in order to prevent forward conduction between the gate 36*g* and source 36*s* of FET 36. With positive voltage applied to electrode 20 the resulting current flow through resistor 40 forward biases the gate to source (36*g* to 36*s*) junction of FET 36 with the voltage drop across resistor 40. If this forward bias voltage is less than the knee voltage (minimum forward gate to source conductive voltage) of FET 36 there will be no significant gate to source current flow. Conversely, however, if a voltage appears across resistor 40 greater than the knee voltage of the forward biased junction, then undesired current will flow between the gate and the source of FET 36, bypassing the resistor 40 and thereby increasing the amount of current through the circuit beyond the limiting value. Because of the above-stated selection of a V_p for FET 34 of less than .5 volt, the voltage across resistor 40 will not exceed .5 volt and thereby forward source to gate conduction of FET 36 is prevented; i.e., the V_p should be less than the knee voltage.

The primary function of FET 32 is to provide a high voltage breakdown capability. If this high voltage FET 32 were not provided, an excessive positive voltage applied to the electrode 20 would cause a voltage breakdown of FET 34. FET 32 protects FET 34 by dropping the excessive voltage. If a sufficiently high voltage FET with suitable V_p characteristics can be provided for FET 34, then FET 32 would not be required. The V_p of FET's 32 and 38 is not critical provided it does not exceed the breakdown voltage of FET's 34 and 36. The components herein have been selected to provide protection against full 220 volt line voltage accidentally being applied to the lead. If high voltages are present in the patient area a higher voltage rating can be provided.

As the circuit 22 is generally symmetrical the operation of the circuit is discussed herein in only one current direction, involving FET's 32 and 34 and the resistor 40. It will be appreciated that this same description also applies to the opposite current direction, involving FET's 38 and 36 and resistor 40. The symmetrical (bi-polar) operation of the circuit is essential for alternating current protection.

For currents significantly below the limiting current value all of the FET's are operating in their linear resistance region and so for these small currents the entire unit operates as a substantially linear resistance. The value of this linear resistance is approximately equal to the value of resistor **40** plus the $Rdss$ values of the four FET's, where $Rdss$ is defined as the small signal drain to source resistance of an FET with the gate connected to the source.

Referring to FIG. 4, the operation of the circuit **22** will be described in both its operating mode and its protection mode. The operating mode is for very small currents flowing though the lead **12** in the order of less than one microampere, and corresponding very low voltage (in the order of millivolts). This is the normal condition when making biomedical measurements as these are the normal lead current levels with body connected electrodes. This mode of operation corresponds to the central linear region of the curve of FIG. 4. The protection mode consists of operation at or near the limiting current with applied voltages exceeding the value causing the limiting current. Excessive voltage conditions can occur as a result of equipment failure, shorts to the leads, shorts to the patient, erroneous connection of equipment, large electrostatic charges, etc.

In the operating mode the resulting voltage across resistor **40** is very small compared to the pinchoff voltage (Vp) of FET's **34** or **36**, so the gate-to-source voltages of both of these transistors are essentially zero as compared to their Vp. As a result the FET's **34** and **36** are operating in their linear resistance region and have very low voltage drops. Only these very low voltage drops across FET's **34** and **36** appear between the gates and sources of FET's **32** and **38**, allowing them also to operate in their linear resistance region. Since there are small voltages involved and no significant reverse bias between the gate and source of any of the four FET's, the linear resistance values are very close to the $Rdss$ values of these FET's. A typical $Rdss$ value for these types of transistors is 1000 ohms, and may be as low as 10 ohms.

The current limiting value is determined by the resistance value of the resistor **40** and the pinchoff voltage Vp (defined above) of FET's **34** and **36**. The FET's **34** and **36** are preferably selected to have the same Vp. The value of resistor **40** is selected so that its resistance is equal to this pinchoff voltage Vp divided by the desired limiting current value. Thus, for the same FET's the current limiting value can be selected or changed merely by changing the value of the resistor **40**. The current limiting value may be set lower for each individual lead or as to limit the total maximum current in all patient leads together to the maximum allowable limit. The resistor **40** is shown in FIG. 3 as variable, although in practice it is preferably a selected fixed resistor.

In describing the protection function of the device or the protection mode, assume a high positive voltage between the patient at electrode **20** and the flexible conductor **24**. Further assume a gradually increasing voltage although an instantaneously applied voltage will be limited in the same manner. As the resulting current increases, the voltage across resistor **40** increases causing the voltage between the source and gate of FET **34** to become increasingly reversed biased. As this voltage approaches the Vp for FET **34**, the voltage drop between the source and drain of FET **34** increases. This source-to-drain voltage of FET **34** in turn appears between the gate and source of FET **32**, reverse biasing it in the same manner. Thus the limiting current value is determined by the combination of resistor **40** and FET **34**, while the major part of the voltage for a high applied voltage is dropped between the drain and source of FET **32**. The maximum voltage which can be applied is the drain-to-gate breakdown voltage of FET **32**. For the assumed polarity FET's **36** and **38** are slightly forward biased and so no significant amount of voltage is dropped across them. It will be obvious that with the opposite polarity (a negative voltage on the electrode **20** with respect to the conductor **24**) that the same protective operation occurs except that the active elements are the FET's **36** and **38**, in conjunction with the resistor **40**.

It may be seen that the current limiting circuit **22** provides high voltage protection (which may be greater than 300 volts with state-of-the-art components) with low and selectible current limiting values yet reasonable low current (operating mode) resistances, e.g., 10K ohms for a ± 100 microamp current limit value, 40K ohms for a ± 10 microamp current limit value, or 300K ohms for a ± 1 microamp current limit value. The limiting currents do not vary significantly with temperature.

Another important characteristic of the lead **12** is that when the lead is operating in the protection mode, the bioelectrical signals stop being conveyed through the lead as soon as the overload occurs. A clamped current level without voltage fluctuations is all that will appear at the input of the biomedical electronic equipment **16**. This immediate absence of bioelectrical input signals can be used to provide an alarm indication. Alternatively, the voltage drop across the circuit **22** can be used to operate an alarm circuit.

Available discrete components are illustrated herein for the circuit **22**. However, it will be readily appreciated that hybrid or integrated circuitry may be employed or other equivalent performance semiconductor devices may be developed which could be substituted herein.

Considering the ground lead **14**, as described above this lead preferably has the same structure and circuitry as instrument lead **12**. The ground lead **14** provides a fast, but current limited, discharge of any electrostatic charges on the patient **18**. A low impedance path to ground is provided through the circuit **22**, both for noise signals on the patient as well as any electrostatic charges. However, the circuit **22** will block current from the patient to ground or vice versa in excess of the preset current limits. This protects, for example, against accidental exposure of the patient **18** to line voltage as well as large electrostatic charges. It may be seen that with this arrangement the patient grounding is much safer, faster and more effective than through a high resistance lead as has been previously utilized.

It may be seen that there has been described herein an improved safety electrode lead system having numerous advantages in both its structure and operation. The apparatus described herein is presently considered to be preferred; however, it is contemplated that further variations and modifications within the purview of those skilled in the art can be made herein. The following claims are intended to cover all such variations and modifications as fall within the true spirit and scope of the invention.

What is claimed is:

1. In a safety electrode lead system for limiting currents therein to less than a very low preset current limiting level for the protection of a patient connected to body electrode meas, the improvement comprising:
   - a conductive electrode lead having first and second ends;
   - said lead having body electrode means at said first end of said lead for receiving electrical currents from a patient;
   - said lead having electrical connector means at said second end of said lead for connection of said lead to other circuitry;
   - said lead including a miniature unpowered semiconductor current limiting circuit mounted in said lead in electrical series connection therewith;
   - said current limiting circuit preventing current flow in both directions through said lead from exceeding a preset current limiting level independent of the polarity and potential of current and voltage applied to said lead;
   - said current limiting circuit providing a substantially

linear impedance conductive path for current from said body electrode means to said connector means through said current limiting circuit for current levels below said preset current limiting level;

said current limiting circuit including in series connection a first field effect transistor with source, drain, and gate leads; a second field effect transistor with source, drain, and gate leads; and voltage dropping means connecting between the source lead of said first field effect transistor and the source lead of said second field effect transistor; wherein each of said field effect transistors has its gate lead connected to its own source lead through said voltage dropping means, and wherein each of said field effect transistors has a low pinchoff voltage.

2. The safety electrode lead system of clam 1 wherein said pinchoff voltage is less than .5 volt.

3. The safety electrode lead system of claim 1 wherein said current limiting circuit is located at said body electrode means.

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WILLIAM E. KAMM, Primary Examiner

U.S. Cl. X.R.

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